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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/381,903	04/17/2000	HELGA KAHLERT	MERCK2034	4568

7590 04/21/2004

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EXAMINER	
NOLAN, PATRICK J	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/381,903	KAHLERT ET AL.	
	Examiner	Art Unit	
	Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9,11-22 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,11-18,20-22 and 24-29* is/are rejected.

7)☒ Claim(s) *9 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Upon further consideration by the Examiner, the indication of allowability of all the pending claims is removed. An office action on the merits is set forth below.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 16 is presently drawn to a pharmaceutical preparation comprising a modified recombinant allergen and an additional active compound. The scope of the term "additional active compound" is unknown and could reasonably read upon thousands of compounds. In reviewing Applicant's specification, there is no specific description as to what species are encompassed by the term, as none are disclosed.

4. Claims 8, 11, 13-18, 20-22 and 24-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a treating grass pollen allergies with a modified recombinant allergen that specifically causes the proliferation of TH_1 T cells in patients allergic to grass pollens and reduces histamine release in basophils from patients allergic to grass pollen when compared with histamine release in basophils challenged with a wild type group 5 Gramineae pollen allergen, does not reasonably provide enablement for treating any allergy with any modified recombinant allergen that comprises at least one immunodominant T cell reactive region from SEQ ID No. 87 (Phl p 5b). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The presently recited broadest claim is drawn to any modified recombinant allergen that comprises at least one immunodominant T cell region from the grass pollen allergen Phl p5b

(SEQ ID NO. 87). The use of these peptides is for allergy therapy. While reviewing the specification and prosecution history it is clear the immunodominant T cell epitopes appear highly homologous amongst the group 5 grass pollen allergens. The purpose of the modified allergen is to reduce histamine release from basophils and switch the immune response from making IgE (a TH_2 immune response) towards IgG (a TH_1 immune response) by removing the IgE epitopes in the wild type allergen via deletion or mutation or substitution, while maintaining the T cell epitopes. The problem with the scope of the claim is that it is limited in its usefulness to grass pollen allergies, since the T cell reactive immunodominant epitopes in the modified recombinant allergen are derived from grass pollen. Since allergy is mediated via IgE, see Figure 16-2 from Kuby et al., and allergies have a wide array of sources for antigens, see Table 16-1 from Kuby et al., in particular, one would not expect that removing the IgE epitopes in grass pollen to reasonably extrapolate to treating penicillin allergies, for example. The reason for this that antibodies bind very specifically to a very limited amount of epitopes, so IgE from grass allergies would not be expected to bind the allergen derived from peanuts, for example (see page 14, 2nd column in Kuby et al). The requirement of maintaining the immunodominant T cell epitopes derived from the group 5 grass pollen allergens, so as to switch from TH_2 to TH_1 limits the usefulness of the invention to treating grass allergies, not every allergy that afflicts humankind. This is because T cell receptors are relatively specific in the type of peptides they will bind. A T helper cell's receptor that is specific for the immunodominant epitopes in group 5 grass allergens would not be expected to bind the immunodominant epitopes found in bee venoms, for example (see page 14, 2nd column in Kuby et al).

5. Claims 9 and 19 are objected as being dependent upon rejected claims.

6. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
April 17, 2004